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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,375

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Takao Suzuki

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HAMRE, SCHUMANN, MUELLER & LARSON P.C.

P.O. BOX 2902-0902

MINNEAPOLIS, MN 55402

EXAMINER

FERNANDEZ, KATHERINE L

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,375

Applicant(s)

SUZUKI ET AL.

Examiner

KATHERINE L. FERNANDEZ

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 9, 2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Varghese et al. (US Patent No. 6,749,571).

With regards to claim 1, Varghese et al. disclose an ultrasonic diagnostic apparatus, comprising: ultrasonic wave transmission/reception means that transmits/receives an ultrasonic wave with respect to a subject (column 3, lines 32-43); a tomographic image processing part that forms a tomographic image representing a structure of the subject based on a reception signal (column 3, lines 44-54, lines 60-67); a tissue characteristic image processing part that forms a tissue characteristic image

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representing a physical characteristic of a tissue of the subject through analysis of the reception signal of plural frames including at least one contraction and/or expansion period of the tissue (column 3, lines 60-67; column 4, lines 8-18; column 5, lines 23-39); memory means (35) that stores the tomographic image and the tissue characteristic image, respectively (column 3, lines 60-67; see Figure 1); an image composing part that combines at least the tomographic image and the tissue characteristic image (column 2, lines 23-39; column 5, line 57-column 6, line 24); display means (32) that displays at least the tomographic image and the tissue characteristic image (column 5, line 57-column 6, line 24; see Figures 1 and 5); and control means (30) that, during an operation of ultrasonic wave transmission/reception, allows the tomographic image to be renewed in an arbitrary cycle, displayed by the display means, and stored in the memory means, while allowing the tissue characteristic image corresponding to at least one contraction and/or expansion period of the tissue to be renewed in a cycle different from the cycle for the tomographic image, displayed by the display means, and stored in the memory means, and during a suspension of ultrasonic wave transmission/reception, allows arbitrary one of the tissue characteristic images that have been acquired previously and one of the tomographic images that is in synchronization with the tissue image to be read out of memory means, respectively and displayed by the display means (column 3, line 60-column 4, line 63; column 5, line 57-column 6, line 16; column 4, lines 8-18).

With regards to claim 8, Varghese et al. disclose that the tissue characteristic image is an image representing a strain or a strain rate (column 4, lines 28-36).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varghese et al. as applied to claim 1 above, and further in view of Von Behren et al. (US Patent No. 6,558,324).

With regards to claim 2, Varghese et al. further disclose that the display means is divided into a first display region and a second display region, and displays at least the tomographic image in the first display region (see Figure 5, column 5, line 57-column 6, line 25). They further disclose that during the operation of ultrasonic wave transmission/reception, the control means allows the tomographic image to be displayed at least in the first display region of the display means, while allowing the tissue characteristic image to be displayed in the second display region of the display means (see Figure 5, column 5, line 57-column 6, line 8), and during suspension of ultrasonic wave transmission/reception, the control means allows the tissue characteristic image and one of the tomographic images that is in synchronization with the tissue characteristic image to be read out from the memory means, respectively and displayed (column 5, line 57-column 6, line 24). With regards to claim 3, Varghese et al. disclose that during the operation of ultrasonic wave transmission/reception, one of

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the tomographic images that is in synchronization with the tissue characteristic image is displayed (column 5, line 57-column 6, line 8). With regards to claim 4, Varghese et al. disclose that during suspension of ultrasonic wave transmission/reception, one of the tomographic images that is in synchronization with the tissue characteristic image is displayed in the first display image (column 5, line 57-column 6, line 8). With regards to claim 5, Varghese et al. disclose that during suspension of ultrasonic wave transmission/reception, the tissue characteristic image that is obtained based on a time period in which the tomographic image displayed in the first display region is included and displayed in the second display region (column 6, lines 9-16). -

However, although they do disclose that the two images may also be superimposed on single display device (column 2, lines 27-29), they do not specifically disclose the display means displays at least the tomographic image on which the tissue characteristic image is superimposed in the second display region, or that during the suspension of ultrasonic wave transmission/reception, the control means allows the tissue characterization image and one of the tomographic images that is in synchronization with the tissue characterization image be displayed at least in the second display region of the display means.

Von Behren et al. disclose a diagnostic ultrasonic imaging method and system, in particular to the display of ultrasonic imaging data relating to the elastic properties (a tissue characteristic) of scanned tissue (column 1, lines 12-15). They disclose that their system displays an elasticity frame overlaid onto a corresponding B-mode image in order to match the strain values to their corresponding tissues (column 13, lines 21-28;

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column 14, lines 10-22). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Varghese et al. to display at least the tomographic image on which the tissue characteristic image is superimposed in the second display region, or display the tissue characterization image and one of the tomographic images that is in synchronization with the tissue characterization image at least in the second display region, as taught by Von Behren et al, in order to match the strain values to their corresponding tissues (column 14, lines 10-22).

6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varghese et al. as applied to claim 1 above, and further in view of Selzer et al. (US Patent No. 6,979,294).

As discussed above, Varghese et al. meet the limitations of claim 1. Further, Varghese et al. disclose that the B-mode images and the elastographic/strain images are linked to an ECG signal (column 4, lines 37-55). However, they do not specifically disclose that the image composing part allows a related waveform that contains information corresponding to at least one of the tomographic image and the tissue characteristic image (i.e. ECG waveform) to be displayed on a display screen of the display means in such a manner as to be combined with the tomographic image and the tissue characteristic image, and during the suspension of ultrasonic wave transmission/reception, the control means allows a portion of the related waveform to be displayed in a highlighted manner, which corresponds to a time period in which the tissue characteristic image being displayed is formed. Selzer et al. disclose a standardized method for obtaining an accurate and reproducible vascular characteristic

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measurement comprising of performing an ultrasonographic examination of vascular structures and capturing ultrasonographic images under a standardized procedure (column 3, lines 39-43). They disclose that a split-screen display is used in which an arterial ultrasound image from an earlier examination is displayed on one half of the screen while a real-time "live" ultrasound image from a current examination is displayed next to the earlier image on the other half of the screen (column 6, lines 51-60). They further disclose that as a further aid in reducing measurement variability, an ECG recording is displayed along a bottom portion (62) of the split-screen display in a manner that allows image frames to be selected based on their occurrence within a particular cardiac cycle, such that the same phase of the cardiac cycle is examined (column 14, lines 5-20; see Figure 6). As seen in Figure 6, a portion of the ECG is displayed in a highlighted manner (i.e. the dotted vertical line on the ECG (62)), which corresponds to a time period in which the image being displayed is formed. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Varghese et al. to have the image composing part allow a related waveform that contains information corresponding to at least one of the tomographic image and the tissue characteristic image (i.e. ECG waveform) be displayed on a display screen of the display means in such a manner as to be combined with the tomographic image and the tissue characteristic image, and during the suspension of ultrasonic wave transmission/reception, the control means allows a portion of the related waveform to be displayed in a highlighted manner, which corresponds to a time period in which the tissue characteristic image being displayed is formed, as taught by

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Selzer et al., in order allow image frames to be selected based on their occurrence within a particular cardiac cycle, thus ensuring that the same phase of the cardiac cycle is examined (column 14, lines 5-20).

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varghese et al. as applied to claim 1 above, and further in view of Nightingale et al. (U.S. Patent No. 6,371,912).

As discussed above, Varghese et al. meet the limitations of claim 1. However, they do not specifically disclose that the tissue characteristic image is an elastic modulus image. Nightingale et al. disclose an ultrasound method and apparatus for the identification and characterization of regions of altered stiffness in a target media (column 1, lines 19-21). They disclose that their invention creates an image of varying stiffness (i.e. increased or decreased elastic modulus) and that their invention can aid in the early detection of breast cancer (column 2, lines 52-57; column 4, lines 32-37; column 1, lines 23-34). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Von Behren et al. to create an elastic modulus image, as taught by Nightingale et al., to aid in the early detection of breast cancer, as taught by Nightingale et al. (column 1, lines 23-34).

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Varghese et al. as applied to claim 1 above, and further in view of Seward (U.S. Patent No. 6,398,736).

As discussed above, Varghese et al. meet the limitations of claim 1. However, they do not disclose that the tissue characteristic image is an image representing a

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viscosity. Seward discloses a catheter apparatus for ultrasonic parametric imaging a visible fourth-dimensional or a non-visible higher-dimensional events in an underfluid environment (column 4, lines 8-42). Seward discloses that ultrasound is used to image viscosity, which provides information about the physiology of the tissue (column 14, lines 12-27; column 1, lines 33-47). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Varghese et al. to create a viscosity image, as taught by Seward, to provide information about the physiology of the tissue (column 1, lines 33-47).

Response to Arguments

9. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

 ERIC F. WINAKUR
PRIMARY EXAMINER